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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/807,200 | ALI ET AL. | |
| | Examiner | Art Unit | |
| | MINH-TAM DAVIS | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview of 03/26/04.
2. ☒ The allowed claim(s) is/are 1.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>03/26/04</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date <u>01/31/02 and 04/10/01</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

It is noted that Applicant's response filed 10/30/03 placed the application in condition for allowance based on the record at that time. The Examiner's Amendment is made in lieu of reopening prosecution in order to remedy informalities which were brought to Applicant's attention for the first time in the telephone Interview of 03/26/04. Accordingly, no further extension of time is required to make the Examiner's Amendment which places the Application fully in condition for allowance.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kathleen Tyrrell on 03/26/04.

The application has been amended as follows:

In the specification.

The following continuation data was inserted to the first line of the specification:

This application is the national stage 371 application of PCT/US99/23764, filed on 10/18/1999.

In the claims.

Claim 1 was amended as follows:

Claim 1 (Amended). A method for diagnosing the presence of prostate cancer in a patient comprising:

(a) measuring the levels of SEQ ID NO:1 ~~or a nucleic acid which encodes a~~
~~protein of SEQ ID NO:2~~ in prostate cells, tissues, ~~or bodily fluids~~ blood, serum, plasma
or urine in a patient; and

(b) comparing the measured levels of SEQ 10 NO:1 ~~or the nucleic acid which~~
~~encodes a protein of SEQ ID NO:2~~ with the levels of SEQ ID NO:1 ~~or the nucleic acid~~
~~which encodes a protein of SEQ ID NO:2~~ in prostate cells, tissues, ~~or bodily fluids~~
blood, serum, plasma or urine from a human control, wherein an increase in the
measured levels of SEQ ID NO:1 ~~or the nucleic acid which encodes a protein of SEQ ID~~
~~NO:2~~ in said patient versus human control at least two times higher than the human
control is indicative of the presence of prostate cancer.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-
272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, CHRISTINA CHAN can be reached on 571-272-0841. The fax phone
number for the organization where this application or proceeding is assigned is 703-
872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

May 25, 2004

SUSAN NGAR, PH.D.
PRIMARY EXAMINER



SUSAN NGAR, PH.D.
PRIMARY EXAMINER